Claims 1-8, 10-13, 15-17 and 52 were rejected as anticipated by U.S. Patent Number 6,299,604 to Ragheb et al. (Ragheb). This rejection is respectfully traversed.

Ragheb discloses a coated implantable medical device. In specific embodiments, the medical device comprises a vascular device such as a stent. In one embodiment, one surface of the stent is coated with a bioactive material, and in another embodiment, a second bioactive material is attached to a second surface of the stent. Porous layers may be placed over the bioactive layers to precisely control the release rate of the bioactive agents. In yet another alternate exemplary embodiment, the stent is coated with a first coating, then a bioactive agent and then the porous coating to control drug release. In the embodiments wherein the stent comprises holes, the bioactive agent is placed in the holes and then coated with the porous layer. In all embodiments set forth in Ragheb, the bioactive layer is never mixed with the porous polymeric layer(s).

The present invention, as claimed in amended independent Claim 1, is directed to a local drug delivery device which comprises a medical device for implantation into a treatment

site of a living organism, at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or the implantation thereof, and a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation. The lubricious material is affixed to at least one of the medical device or a delivery system for the medical device. The present invention, as claimed in amended independent claim 52, is directed to a local drug delivery apparatus which comprises a medical device for implantation into a treatment site of a living organism, at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof, and a water soluble powder for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site. The water soluble material being affixed to at least one of the medical device or a delivery system for the medical device.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Applicants respectfully submit that Ragheb fails to disclose or even remotely suggest a medical device, a therapeutic agent incorporated into a polymeric matrix and a separate lubricious material or water soluble powder for preventing the at least one

agent from separating from the medical device prior to implantation. The Examiner correctly asserts that polymeric coatings may be lubricious; however, the claims as amended now have a polymeric matrix and a separate lubricious material. In addition, Ragheb teaches away from the present invention by stating that the polymeric layers be separate and distinct from the bioactive material layers, see column 19, lines 44-52. Since Ragheb fails to disclose or suggest all of the claim limitations, there is no *prima facie* case of obviousness. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12-14, 17 and 28-36 of copending Application No. 09/962,496.

Applicants understand that this rejection is to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the amendment to the claims of the present invention and any potential amendments made to the claims of the cited

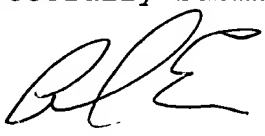
application, Applicants shall defer any arguments and/or actions until the applications actually issue.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

The Amendment/Reply raises no new issues and places the application in form for allowance. Therefore, entry is proper and earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

1. (Twice Amended) A local drug delivery apparatus comprising:

a medical device for implantation into a treatment site of a living organism;

at least one agent in therapeutic dosages incorporated in a polymeric matrix and [releasably] affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof; and

a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the lubricious material being affixed to at least one of the medical device or a delivery system for the medical device.

52. (Amended) A local drug delivery apparatus comprising:

a medical device for implantation into a treatment site of a living organism;

at least one agent in therapeutic dosages incorporated in a polymeric matrix and [releasably] affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof; and

a water soluble powder for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the water soluble material being affixed to at least one of the medical device or a delivery system for the medical device.